

REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

I. Substance of the Interview Statement

Applicants would like to thank the Examiner for the interview with Applicants' representative on June 16, 2008, regarding the present invention and proposed Examiner's amendments to the claims. As noted in the Interview Summary attached to the June 23, 2008 Office Action, an agreement with respect to the claims was not reached, and the Examiner agreed to issue an Office Action based on the claims and arguments as set forth in Applicant's March 11, 2008 response.

II. Claim Amendments

By the foregoing amendments to the claims, claims 1, 2, 5, and 14-16 have been amended.

In particular, claim 1 has been amended by replacing the terms "establishing a primary discriminator" and "establishing a secondary discriminator" with the terms "defining a primary population" and "defining a secondary population." The defining of these populations is described throughout the application as filed, for example in Figures 1(a) and 1(b). In addition, the claim has been amended to encompass an alternative method for determining the absolute number of CD4⁺ lymphocytes, which is to count them directly without first counting the CD45⁺ cells. Support for this alternative method can be found at least at page 17, line 32, to page 18, line 4, of the present specification.

Further amendments to the claims have also been made to clarify the claim language, for consistency, and to bring the claims into better conformance with U.S. patent practice. These amendments are merely editorial in nature and are not intended to change the scope of the claims or any elements recited therein.

The amendments to the claims have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicant reserves the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new

matter has been added, and entry of the foregoing amendments to the above-identified application is respectfully requested.

III. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph

At pages 2-3 of the Office Action, claims 1, 2, 5, and 14-16 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement.

In particular, the Examiner has stated that the term "discriminator" and the phrase "discriminator to discriminate" are not adequately described in the specification.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, the claims have been amended as described above. Applicants submit that a person of ordinary skill in the art at the time of filing would have known how to define the cell populations recited in the present claims using flow cytometry, for example by using a gate, a threshold, and/or a discriminator. Therefore, the claims as amended herein are adequately supported by the present application.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

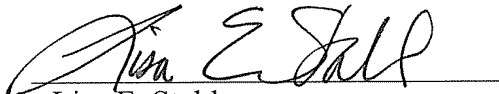
In the event that there are any questions relating to this Reply or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney so that prosecution of this application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: November 21, 2008

By:

A handwritten signature in black ink, appearing to read "Lisa E. Stahl", is written over a horizontal line.

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